REMARKS

Review and reconsideration on the merits are requested.

The prior art: U.S. Patent 5,294,444 Nakamura et al (Nakamura); WO 98/27958 Kaneko et al (Kaneko et al); U.S. Patent 5,476,661 Pillai et al (Pillai); U.S. Patent 6,348,201 Murata (Murata).

All anticipation rejections are under 35 U.S.C. § 102(b) and all obviousness rejections are under 35 U.S.C. § 103(a).

The rejections (in the order posed):

Claims 1, 2, 4-8 and 11 as anticipated by Nakamura.

Claims 1-3 and 5-11 as anticipated by Kaneko.

Claims 1-3 and 5-11 as anticipated by Pillai.

Claims 1, 2, 4-8 and 11 as obvious over Nakamura.

Claims 1-11 as obvious over Nakamura in combination with Murata.

Claims 1-3 and 5-11 as obvious over Kaneko.

Claim 4 is obvious over Kaneko in view of Nakamura.

Claims 1-3 and 5-11 is obvious over Pillai.

Claim 4 is obvious over Pillai in view of Nakamura.

The Examiner's position is set forth in the Action and will not be repeated here except as necessary to understand Applicants' traversal which is now presented.

As the Examiner will see, the claims have been changed from the "comprising" format to the --consisting essentially of-- format. This is to make it clear that the ceramide composition of

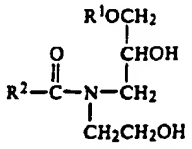
claim 1, the method of claim 7 and the lipid composition of claim 11 do not involve the use of an ionic surface active agent.

Applicants first address Nakamura.

With respect to Nakamura, the Examiner's position appears to be that Nakamura discloses a transparent cosmetic composition comprising a ceramide, a nonionic surfactant, and anionic surfactant and an aqueous medium.

Nakamura may, in fact, disclose a transparent cosmetic composition comprising an amphipathic lipid, a non-ionic surfactant, an ionic surfactant, a long-chain fatty acid and an aqueous medium (Nakamura, Examples 21 to 28 of Table 3).

However, as is clear from Examples 1 to 28 in Nakamura, the amphipathic lipids used in Nakamura are amide derivatives which have the structure described at col. 2, lines 36-51 of Nakamura, namely:



wherein R^1 is $C_{16}H_{33}$ and R^2 is C_9H_{15}, clearly different from a true ceramide as called for and claimed in the present application.

At page 2 of the present specification, the following disclosure occurs:

> However, ceramides are highly crystalline high-melting compounds and, because of their peculiar amphiphatic structure, have extremely low solubility in most of oil soluble or water-soluble bases (solvents) for cosmetics. For this it has been difficult to formulate ceramides into stable preparations. That is, preparations having a high ceramide content easily undergo precipitation, or some

lubricants which are used to dissolve a larger amount of a ceramide are unfavorable for safety.

Thus, it is seen that the ceramides of the present invention are highly crystalline high melting point compounds and, because of their peculiar amphiphatic structure, they have extremely low solubility in most oil-soluble or water-soluble bases (solvents).

Ceramide 2 (Optically active ceramide (a)) and Ceramide 5 (Optically active ceramide (b)) (see Tables 1 and 3) used in the present invention have the following melting points see U.S. Patent No. 5,831,125(copy attached).

Optically active ceramide (a):
(2S,3R)-2-Octadecanoylaminooctadecane-1,3-diol
M.P. 105-106°C
(see Ex. 4 of U.S. Patent No. 5,831,125)
Optically active ceramide (b):
(2S,3R)-2-(2-hydroxyhexadecanoyl)aminooctadecane-1,3-diol
M.P. 112-122°C
(see Ex. 9 of U.S. Patent No. 5,831,125)

Although the melting point of the racemic ceramide (Racemic ceramide (c)) is not given in U.S. Patent No. 5,831,125, the optically active compound thereof (Ex. 4) has a melting point of 105-106°C and the compound of Example 1 having a smaller number of carbon atoms by 2 has a melting point of 96.7-98.2°C. The melting point of the racemic ceramide is believed to be on this level.

In distinction, the amide compound of Nakamura is has a melting point of 74.9-75.3°C from Ex. 1 of U.S. Patent No. 4,778,823 (copy attached). The melting point of the compounds having a different number of carbon atoms is at most 76°C (see Examples 2-7). Thus, the amide

compounds of Nakamura have a melting point about 20°C lower than that of the ceramides of the present invention. Because the amide compounds of Nakamura have such relatively lower melting points, they have relatively low crystallinity. This is quite in distinction to the ceramides of the present invention which are highly crystalline, high melting point compounds which, because of their peculiar amphiphatic structure, have extremely low solubility in most oil-soluble or water-soluble basis (solvents).

The composition of Nakamura is as follows (claim 1):

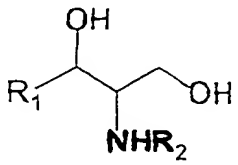
> Claim 1. A cosmetic composition comprising: (A) 0.05-30% by weight of an amphipathic lipid selected from the group consisting of a ceramide, a derivative of a ceramide, a glycolipid, a derivative of a glycolipid, and a mixture thereof, (B) 0.05-30% by weight of a nonionic surfactant, (C) 1-50% by weight, based on (B), of an ionic surfactant, and (D) 40-99% by weight of an aqueous medium, wherein said composition is transparent or semi-transparent, and wherein the ratio of (A)/[(B) + (C)) is 0.2-10.

A "+" has been added to the end of claim 1 since this appears to be an obvious omission in claim 1 of Nakamura. Thus, in Nakamura it seems to be a combination of (A) an amphipathic lipid, (B) a nonionic surfactant, (C) an ionic surfactant and (D) an aqueous medium which is the point of invention. Among these Nakamura components, (C) an ionic surfactant, is not preferably used for cosmetics because of the possibility of skin irritation. This is disclosed on page 3 of the present specification:

> However, the amphipathic lipids that are actually used are pseudoceramides. In addition, there is a fear of skin irritation due to the ionic surface active agent which is not preferred for cosmetics.

The ceramide composition of the present invention is as follows:

A clear aqueous ceramide composition comprising (now -- consisting essentially of...) (A) 1.0 to 5.0% by weight, based on the total composition, of a ceramide represented by formula (I)



(I)

wherein R^1 represents a hydrocarbon group having 9 to 17 carbon atoms; and R^2 represents an acyl group having 2 to 30 carbon atoms which can contain a hydroxyl group, (B) a long-chain fatty acid having 12 to 24 carbon atoms, (C) a nonionic surface active agent, and (D) water.

Thus, the present invention is based on the combination of (A) a ceramide represented by formula (I), (B) a long-chain fatty acid, (C) a nonionic surface active agent and (D) water. An ionic surfactant is not used in the present invention. Although an ionic surfactant (Sodium POE (4) lauryl ether phosphate) is used in APPLICATION EXAMPLE 1, this was merely an example of a further application of the invention and the same is not preferred. The present invention achieves the objects of the invention by the use of a long chain fatty acid, not by an ionic surfactant.

Withdrawal of the anticipation rejection over Nakamura is requested, as is withdrawal of any obviousness rejection based in whole or in part on Nakamura.

Turning now to Kaneko, the Examiner's position appears to be that Kaneko discloses a protective agent for skin and hair comprising a specific ceramide, a surface active agent, a higher fatty acid and a lipid.

However, in no fashion does Kaneko teach a composition which is "clear" and "aqueous" which are requirements set forth in the claims of the present application.

Referring to Kaneko at page 8, lines 12-21, the following disclosure occurs:

> The erythro (2S,3R) type of ceramide-II mixed as described above may be, if desired, used as cosmetics in the form of a liposome solution, an emulsion, a water-alcohol solution, an oily solution, or an oil-alcohol solution, a gel, a dispersion, a solid stick, a spray or an aerosol. Examples of these cosmetics include a conditioner, a face lotion, a milky lotion, a cream, a beauty lotion and the like."

However, water is not mentioned. In addition, in Examples, Kaneko does not show whether it is possible to obtain dissolution in aqueous media to provide a clear solution. In the detailed discussion in Kaneko, surface active agents (nonionic surface active agents) and higher fatty acids are described but there is no Example that actually combines these components.

Further, Kaneko in no fashion discloses or suggests the technical concept of dissolving the components of the Kaneko system into water, i.e., water is nowhere described as a solvent in Kaneko and request withdrawal of the anticipation rejection and any obviousness rejection based in whole or in part on Kaneko.

Applicants now turn to Pillai.

It appears to be the Examiner's position that Pillai discloses a topical composition for hair, skin or nails which comprises a ceramide, a nonionic surfactant, and ionic surfactant, cholesterol and water.

However, and importantly, Pillai does not teach or suggest "clear" and "aqueous" which are requirements of the present invention. The amount of ceramide used in Example 4 (0.1%), in Example 5 (0.1%), in Example 6 (0.025%), in Example 7 (0.01% + 0.01% = 0.02%), and in Example 8 (0.01% + 0.01% = 0.02%). Thus, the amount of ceramide used in Pillai is much lower than the specific amount of ceramide of the present invention (1.0 to 5.0%). Example 10 (1.5%) and Example 11 (0.5%) of Pillai used neoceramide, which is not a true ceramide. As explained in Nakamura (of record), neoceramide is an easily soluble compound, which is clearly different from the specific ceramides of the present invention.

The present invention is characterized in that a true ceramide is dissolved in an aqueous medium in a high concentration as a clear solution. Thus, Pillai, which uses a ceramide in a lower concentration, does not teach or suggest the present invention.

Withdrawal of any anticipation rejection or any obviousness rejection based in whole or in part Pillai is requested.

The Examiner has rejected claims 1-11 based on the combination of Nakamura and Murata. The Examiner asserts that Murata discloses that higher fatty acids are anionic surfactants.

However, higher fatty acids themselves are not anionic surfactants. When they are made into salts (i.e., salts of higher fatty acids), the salts can be anionic surfactants. The present invention does not use any salt of a higher fatty acids and does not contain a component which would transform a fatty acid into a salt. In other words, the present invention does not contain anionic surfactants.

Therefore, even assuming that Nakamura and Murata could be combined, the present invention is not taught or suggested.

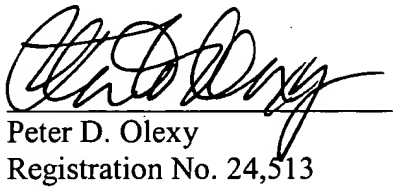
Withdrawal of all art rejections is requested.

Applicants rely upon their arguments above regarding the anticipation rejections based on Nakamura, Kaneko and Pillai to also traverse the obviousness rejections based on Nakamura, Kaneko and Pillai in whole or in part, and with respect to the obviousness rejections of claim 4 over Kaneko in view of Nakamura and Pillai in view of Nakamura, Applicants rely on their arguments above.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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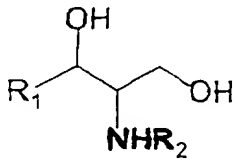
APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The claims are amended as follows:

1. (Amended) A clear aqueous ceramide composition [comprising] consisting essentially of (A) 1.0 to 5.0% by weight, based on the total composition, of a ceramide represented by formula (I):

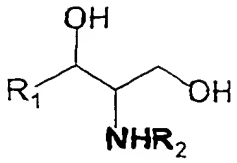


(I)

wherein R_1 represents a hydrocarbon group having 9 to 17 carbon atoms; and R_2 represents an acyl group having 2 to 30 carbon atoms which can contain a hydroxyl group,

(B) a long-chain fatty acid having 12 to 24 carbon atoms, (C) a nonionic surface active agent, and (D) water.

7. A method of preparing a clear aqueous composition [comprising] consisting essentially of 1.0 to 5.0% by weight of a ceramide represented by formula (I):

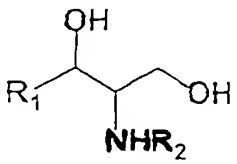


(I)

wherein R_1 represents a hydrocarbon group having 9 to 17 carbon atoms; and R_2 represents an acyl group having 2 to 30 carbon atoms which can contain a hydroxyl group,

comprising adding water to a lipid composition [comprising] consisting essentially of (A) said ceramide, (B) a long-chain fatty acid having 12 to 24 carbon atoms, and (C) a nonionic surface active agent, whereby said lipid composition upon combination with water will yield a clear aqueous ceramide composition.

11. (Amended) A lipid composition for preparing a clear aqueous ceramide composition, the lipid composition [comprising] consisting essentially of (A) a ceramide represented by formula (I):



(I)

wherein R_1 represents a hydrocarbon group having 9 to 17 carbon atoms; and R_2 represents an acyl group having 2 to 30 carbon atoms which can contain a hydroxyl group,

(B) a long-chain fatty acid having 12 to 24 carbon atoms, and (C) a nonionic surface active agent, wherein the weight ratio of component (A) to component (B) is from 20:1 to 1:3, and the weight ratio of component (A) to component (C) is from 1:1 to 1:10.